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| EXAMINER | |
|---|---|
| HOFFA, ANGELA MARIE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3768 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/549,881 | KEENAN, JAMES | |
| | Examiner | Art Unit | |
| | Angela M. Hoffa | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *50-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. This office action is in response to communication filed on January 16, 2007.

### *Priority*

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

### *Drawings*

3. The drawings are objected to because Figure 9A includes box 15, 54, and 3 that are not properly labeled. References numerals alone are considered to be insufficient.

### *Specification*

4. The abstract of the disclosure is objected to because of a minor informality. Please add a period to end of second paragraph on Page 8. Correction is required. See MPEP § 608.01(b).

### *Claim Objections*

5. Claims 57 and 69 are objected to because of the following informalities: Claim 57, "devce" in Line 1 is spelled incorrectly. Claim 69, the limitation "a second transducer" is defined in Line 1; however, there is no previously defined "first transducer". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 50-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, the “fluid supply” component E appears to have already been defined in Lines 4-6 of component B as “a fluid”. Clarification is needed. Similarly, Claim 66 need clarification on “a second fluid supply” since "a second fluid" is previously defined in Line 6. Claim 79 requires the same clarification regarding the fluid supply.

Claim 1 recites the limitation "the discharge end" in Line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 recites the limitations "the drive mechanism" and “the actuator” in Line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 56 recites the limitation "the fluid volume" in Line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 65 recites the limitation "the valve member" in Line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 69 recites the limitation "the controller" in Line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 79 recites the limitation “the device” in Line 4. It is unclear as to what device it is referring since "a medical device" is defined in both Lines 3 and 4.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim*s* 50-61, 65-68, 70-75, 77, and 79 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,471,674 B1 to *Emig et al*.

Regarding Claim 50, *Emig et al* discloses a medical device for fluid delivery comprising:

- a fluid container having a discharge end (syringe 300, outlet 310, Figure 1);
- a fluid discharge device disposed in connection with the fluid container that applies a selected pressure for ejecting said fluid from the reservoir through the discharge end (plunger, Col. 2, Lines 54-67 or motor, Col. 7, Lines 3-12);
- a first conduit having an entrance end and an exit end and defining a first passage therebetween, the entrance end disposed at the discharge end of the fluid container, the first passage in communication with the reservoir (connector 420, tubing 250, Figure 1);
- a needle having a connector end and a distal tip and defining a needle passage therebetween, the connector end in communication with the exit end of the first

conduit, the needle passage in communication with the first passage (disposable patient interface 200A, Figure 1; intravenous catheter Col. 4, lines 21);

- a fluid supply operatively connected to the fluid discharge device selectively applying the selected pressure to the fluid (pre-filled contrast, Figure 1);
- wherein the selected pressure is capable of moving the fluid through the discharge end of the fluid container and traveling a first flow path through the first passage and through the needle passage, capable for ejection of the fluid at the distal tip at a fluid flow rate suitable for detection by ultrasound (Col. 3, Lines 61-64).

Regarding Claims 51 and 52, 55, 56, *Emig et al* further discloses wherein the fluid includes an echogenic fluid (contrast media, Col. 3, Line 60) or a therapeutic agent (Col, 7, Line 9) with a controller electrically connected to a drive mechanism and to an actuator for selectively applying the selected pressure and thereby controlling the fluid flow rate (Col. 7, Lines 5-6; Col. 6, Lines 27-42).

Regarding Claims 53-54, *Emig et al* further discloses wherein the fluid supply comprises a drive mechanism operatively connected to the fluid discharge device and an actuator for the selective operation of the drive mechanism that is mechanized (Col. 7, Lines 5-12).

Regarding Claim 57, *Emig et al* further discloses wherein the fluid container is a syringe (syringe 300) and the fluid discharge device is a plunger slidably disposed with the syringe (plunger, Col. 2, Lines 54-67).

Regarding Claim 58, *Emig et al* further discloses a valve member disposed at a selected position on the first conduit, said valve member having a seal capable of

selectively reducing or stopping throughput of the fluid into or within the first passage (one-way check valve 410, 240, Figure 1).

Regarding Claim 59, *Emig et al* further discloses wherein the valve member is disposed at the entrance end of the first conduit (check valve 410, Figure 1).

Regarding Claim 60, *Emig et al* further discloses wherein the valve member is a one-way valve member for permitting fluid flow into the first passage and to prevent fluid flow in the reverse direction into the discharge end of the fluid container (check valve 410, Figure 1).

Regarding Claim 61, *Emig et al* further discloses an adaptor for releasable coupling of the connector end of the needle to the exit end of the first conduit, the adaptor defining an adaptor passage for maintaining communication between the needle passage with the first passage (Luer connectors 270, 260, Figure 1).

Regarding Claim 65, *Emig et al* further discloses a port connection (Luer connection 440, Figure 1), a second conduit having a second entrance end and a second exit end and defining a second passage therebetween (tubing 430, Figure 1), the second exit end disposed at the port connector, a second connector disposed at the second entrance end for connection for the second entrance to a selected medical component (Luer connection 460, Figure 1), wherein the port connector is disposed at a selected portion of the first conduit or at a valve member for permitting communication between the second passage and the first passage (Figure 1).

Regarding Claim 66, *Emig et al* further discloses a second fluid container (syringe 500, Figure 1) having a second discharge end (outlet 510, Figure 1), a second

fluid discharge device disposed in connection with the second fluid container so as to define a second fluid retaining reservoir (plunger, Col. 2, Lines 54-67 or motor, Col. 7, Lines 3-12), the second discharge device configured to apply a second selected pressure to a second fluid in the second fluid retaining reservoir for ejecting said second fluid from the second reservoir through the second discharge end, wherein the second selected pressure is capable of ejecting the second fluid through the second discharge end of the second fluid container and traveling a second flow path through the second passage, through to one of the valve member or to the selected portion of the first passage, and through the needle passage, for ejection at the distal tip at a second flow rate (Figure 2E).

Regarding Claims 67-68, *Emig et al* further discloses the second fluid supply comprising a second drive mechanism operatively connected to the second fluid discharge device and a second actuator for the selective operation of the second drive mechanism wherein the second actuator is mechanized (motor, Col. 7, Lines 3-12);.

Regarding Claims 70-72, *Emig et al* further discloses a switch configured for switching actuation of the first fluid supply and the second fluid supply (by hand, plunger, Col. 2, Lines 54-67 or motor, Col. 7, Lines 3-12, See Figures 2D-2E), wherein the second fluid is a therapeutic contrast agent (saline, contrast agent, or other therapeutic agent, Col. 7, Line 9).

Regarding Claim 73-75, *Emig et al* further discloses a vacuum source (aspiration port 230, Col. 4, Lines 19-26; inherently present vacuum source in order to perform function) capable of tissue aspiration, capable of performing a biopsy, and capable in

fluid or material drainage, and also includes a catheter capable of supplying fluids (intravenous catheter, Col. 4, Line 21).

Regarding Claim 77, *Emig et al* further discloses an adaptor capable of supporting an ultrasound probe (port 230, Figure 1).

Regarding Claim 79, *Emig et al* discloses an ultrasonic guided positioning method for detecting a medical device comprising:

- dispensing a fluid from a distal tip of a needle of a medical device (Col. 2, Lines 54-55), the fluid having a selected flow rate for detection by a medical device (Col. 3, Lines 59-64), the device having the features used in the rejection for Claim 50 above;
- transmitting an ultrasonic pulse from an ultrasound transducer, receiving the ultrasound pulse by the ultrasound transducer; and detecting the fluid ejected from the distal tip (Col. 1, Lines 15-52, Col. 3, Lines 59-64, intended use of device to be applied to timed bolus detection, Col. 6, Lines 47-49).

## ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Emig et al* as applied to Claim 61 above in view of U.S. Patent Publication No. 2002/0188201 A1 to *Crowley.*

*Emig et al* provides an aspiration port 230 in Figure 1, but does not expressly disclose wherein said port is releasably coupled to a probe within the passageway.

However, *Crowley* discloses an ultrasonic catheter imaging probe to provide therapeutic heating to tissue via radio frequency (Par. 0150) in order to soften plaques (Par. 0135).

It would have been obvious to one of ordinary skill in the art at the time of invention to use the aspiration port 230 of *Emig et al* to insert various therapeutic probes such as a RF heating probe in order to soften plaques as taught by *Crowley* (Par. 0135).

13. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Emig et al* as applied to Claim 66 above in view of U.S. Patent Publication No. 2004/0215080 A1 to *Lechner.*

*Emig et al* does not expressly disclose a transducer for sensing the selected pressure applied to the fluid and for outputting an electrical signal reflective of the selected pressure for input to a controller.

However, *Lechner* discloses a pressurized injection device that measures fluid injection pressure via a transducer and outputs an electrical signal reflective of the measured pressure in order to measure the injection pressure into a body cavity (Par. 0006).

It would have been obvious to one of ordinary skill in the art at the time of invention to use a pressure transducer to measure the injection pressure as taught by *Lechner* in order to prevent device failure as suggested by *Emig et al* (Col. 1, Lines 24, 46-47).

14. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Emig et al* as applied to Claim 50 above in view of U.S. Patent Publication No. 2002/0188201 A1 to *Crowley.*

*Emig et al* does not expressly disclose a device comprising an ultrasound transducer transmitting an ultrasound pulse or continuous ultrasound through the needle passage, but does provide an insertion means for tissue aspiration devices (port 230, Figure 1).

However, *Crowley* discloses a liquid-filled disposable catheter with an ultrasound transducer disposed upon its distal end which sends ultrasonic pulses through the passageway in order to image tissue Abstract, Figure 1).

It would have been obvious to one of ordinary skill in the art at the time of invention that the system of *Emig et al* could be used in conjunction with the probe of *Crowley* in order to image tissue (Abstract). The probe could be easily inserted into the port 230 of *Emig et al.*

15. Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Emig et al* as applied to Claim 50 above in view of U.S. Patent Publication No. 2003/0135119 A1 to *Lee et al.*

*Emig et al* does not disclose detecting a medical device via ultrasound but does disclose the device as in the rejection for Claim 50.

*Lee et al* shows that it is common in the art to detect a medical device via ultrasound using the system of an ultrasound transducer for transmitting and receiving pulses, an ultrasound display, and a system controller connected to other components to control, detect, and display the location of the distal tip of the needle on the ultrasound display (Figure 1-2, Abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to track a medical device with ultrasound in order to identify its position as taught by *Lee et al.*

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Hoffa whose telephone number is 571-270-7408. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M. H./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768